IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, et al.,	:	
Plaintiffs,	:	
v.	:	Civil Action No. 14-777-RGA
MYLAN INC., et al.,	:	
Defendants.	:	

NOVARTIS PHARMACEUTICALS CORPORATION, et al.,	:	
Plaintiffs,	:	
v.	:	Civil Action No. 14-820-RGA
MYLAN INC., et al.,	:	
Defendants.	:	

MEMORANDUM

I have pending motions to dismiss for lack of personal jurisdiction in the two above-captioned cases, filed by Defendants Mylan Inc. and Mylan Pharmaceuticals Inc. (No. 14-777-RGA, D.I. 14; No. 14-820-RGA, D.I. 14).

Background.

On November 3, 2011, Novartis Pharmaceuticals Corp., Novartis AG, Novartis Pharma AG, Novartis International Pharmaceuticals Ltd., and LTS Lohmann Therapie-Systeme AG

(collectively, "Novartis") filed an ANDA suit against Actavis South Atlantic LLC and Actavis, Inc. (No. 11-1077-RGA). Novartis Pharmaceuticals Corp. is a Delaware corporation with a principal place of business in New Jersey. The other Novartis corporations are Swiss, Bermudan, or German, with principal places of business in those countries. (No. 11-1077-RGA, D.I. 1, ¶¶ 2-6). Novartis asserted three patents (the '176, the '023, and the '031) which protected its branded Exelon Patch product, a rivastigmine transdermal patch. Actavis South Atlantic is a Delaware limited liability company with a place of business in Florida, and Actavis, Inc. is a Delaware corporation with a place of business in New Jersey. (*Id.*, ¶¶ 7, 8). Par later was substituted in for Actavis. (No. 11-1077-RGA, D.I. 196). I held a fourteen hour trial in May 2014, and ruled in Par's favor on August 29, 2014. (No. 11-1077-RGA, D.I. 426). The case (including related case Nos. 13-371-RGA, 13-1467-RGA, and 14-843-RGA) is now on appeal to the Federal Circuit. (Nos. 15-1061, 15-1062, 15-1120 & 15-1121).

On November 9, 2011, Novartis filed an ANDA suit against Watson Laboratories, Inc., Watson Pharma, Inc., and Watson Pharmaceuticals, Inc., asserting the same patents against a proposed rivastigmine transdermal patch. (No. 11-1112-RGA). Watson Pharma, Inc. is a Delaware corporation having a place of business in New Jersey. (No. 11-1112-RGA, D.I. 1, ¶ 8). The other two defendants are Nevada corporations with places of business in New Jersey. (*Id.*, ¶¶ 7, 9). I held a twenty-one hour trial in August 2013, and ruled in Novartis's favor on June 18, 2014. (No. 11-1112-RGA, D.I. 40). The case is now on appeal to the Federal Circuit. (Nos. 14-1799, 14-1800, 15-1141).

On January 4, 2013, Novartis filed an ANDA suit against Alvogen Pine Brook, Inc., and Alvogen Group, Inc. asserting the '023 and '031 patents against a proposed rivastigmine

transdermal patch. (No. 13-52-RGA). Both defendants are Delaware corporations with places of business in New Jersey. (No. 13-52-RGA, D.I. 1, ¶¶ 7, 8). The case (including a related case, No. 13-370-RGA) was resolved by agreement in July 2014. (No. 13-52-RGA, D.I. 177, 178).

On April 3, 2013, Novartis filed an ANDA suit against Noven Pharmaceuticals, Inc., Noven Therapeutics, LLC, and Hisamitsu Pharmaceutical Co., Inc., asserting the '023 and '031 patents against a proposed rivastigmine transdermal patch.[1] (No. 13-527-RGA). The Noven defendants are Delaware corporations with places of business in Florida. Hisamitsu is a Japanese corporation. (D.I. 13-527-RGA, D.I. 1, ¶¶ 7-9). I held a fourteen hour trial in December 2014, and the case (including a related case, No. 14-111-RGA) is now under advisement.

On June 19, 2014, four of the five Novartis corporations filed an ANDA suit against Mylan Inc. and Mylan Pharmaceuticals Inc., asserting the '023 and '031 patents against a proposed rivastigmine transdermal patch.[2] (No. 14-777-RGA). Mylan Inc. is a Pennsylvania corporation having a place of business in West Virginia, and Mylan Pharmaceuticals Inc. is a West Virginia corporation having a place of business in West Virginia. (No. 14-777-RGA, D.I. 1, ¶¶ 6, 7). Mylan has filed a motion to dismiss for lack of personal jurisdiction. (No. 14-777-RGA, D.I. 14). On June 20, 2014, Novartis filed an ANDA suit asserting the same patents against Mylan in the Northern District of West Virginia. (NDWV No. 14-cv-106-IMK, D.I. 1).

On August 27, 2014, four of the five Novartis corporations filed an ANDA suit against Zydus Noveltech Inc., Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd., asserting the '023 and '031 patents against a proposed rivastigmine transdermal patch. (No. 14-1104-

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[1] Noven is the petitioner in pending IPRs on the two patents. IPR2014-00549/00550.

[2] Mylan is the petitioner in pending IPRs on the two patents. IPR2015-00265/00268.

RGA). The Zydus defendants are New Jersey corporations with principal places of business in either Vermont or New Jersey, and Cadila is an Indian corporation. (No. 14-1104-RGA, D.I. 1, ¶¶ 6-8). They have filed a motion to dismiss for lack of personal jurisdiction and on other grounds. (No. 14-1104-RGA, D.I. 14). The only briefing so far has been Defendants' opening brief, but that brief does state that the day after filing this case, Novartis filed "an identical complaint" against Defendants in New Jersey. (No. 14-1104-RGA, D.I. 15, p.1).[3]

The Mylan defendants, meanwhile, have been being sued in Delaware in other ANDA cases, and, at least recently, have been filing motions to dismiss for lack of personal jurisdiction. Most of the motions have been resolved. *See AstraZeneca AB v. Mylan*, 2014 WL 5778016 (D. Del. Nov. 5, 2014); *Acorda Therapeutics, Inc. v. Mylan Pharmaceuticals Inc.*, 2015 WL 186833 (D. Del. Jan. 14, 2015); *Forest Labs, Inc. v. Amneal Pharmaceuticals LLC*, 2015 WL 880599 (D. Del. Feb. 26, 2015). Judge Sleet has certified *AstraZeneca* for interlocutory appeal. (No. 14-664-GMS, D.I. 103). So too has Chief Judge Stark in *Acorda*. (No. 14-935-LPS, D.I. 36). Permission to appeal the *AstraZeneca* and *Acorda* cases is pending in the Court of Appeals. (Fed. Cir. Nos. 15-117 & 15-124).

Decision.

I received supplemental submissions following the *Acorda* ruling. (No. 14-777-RGA, D.I. 33, 34, 36, 38, 40, 46, 47).

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[3] There is less background to the 14-820 case. On one previous occasion, four Novartis entities sued four Actavis defendants relating to generic deferasirox tablets, asserting the '504 and '750 patents. (No. 12-366-RGA-CJB). Two of the Actavis defendants were Delaware corporations with principal places of business in New Jersey. While the case was assigned to me, it was referred to Magistrate Judge Burke and I had little substantive involvement in the case until shortly before trial, at which time the case settled. The 14-820 case involves proposed generic deferasirox tablets and the same two asserted patents as the 12-366 case.

I am not sure I have anything to add to what my colleagues have already said. The factual history of the rivastigmine litigation, recited above, parallels very closely with the litigation history in *Acorda*. On the general jurisdiction question, I am going to follow *Acorda* and *Forest Labs*. I will explain briefly my reasons for doing so.

First, the Delaware registration statutes require consent to general jurisdiction. *See Sternberg v. O'Neil*, 550 A.2d 1105, 1116 (Del. 1988). Thus, as a factual matter, Mylan Pharmaceuticals Inc. has consented to general jurisdiction.

Second, at least two courts of appeals have expressly upheld, albeit not that recently, the validity of such registration statutes as the basis for consent to general jurisdiction. *See Bane v. Netlink, Inc.*, 925 F.2d 637, 640-41 (3d Cir. 1991); *Knowlton v. Allied Van Lines, Inc.*, 900 F.2d 1196, 1199-1200 (8th Cir. 1990).[4]

Third, I have considered *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014), and *Goodyear Dunlop Tires Ops, S.A. v. Brown*, 131 S. Ct. 2846 (2011). In reading those cases and trying to make sense of them, I think the broad language of the opinions has to be read in the context of the limiting language. For example, *Daimler* begins, "This case concerns the authority of a court in the United States to entertain a claim brought by foreign plaintiffs against a foreign defendant based on events occurring entirely outside the United States." 134 S. Ct. at 750.[5] *Daimler* later

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[4] Questions of personal jurisdiction in patent cases are decided under Federal Circuit law. *See Acorda*, 2015 WL 186833, at *5 n.5. There are other courts of appeals that have disagreed with *Bane* and *Knowlton*. *See Wilson v. Humphreys (Cayman) Ltd.*, 916 F.2d 1239, 1245 (7th Cir. 1990) (declining to read Indiana's registration statute as a basis for general jurisdiction, stating that to do so would be "constitutionally suspect" and not satisfy "the demands of due process," but not specifically addressing consent).

[5] *Goodyear* involved domestic plaintiffs bringing suit against foreign defendants for an accident that happened in France. 131 S. Ct. at 2850.

phrases the issue presented as, "whether, consistent with the Due Process Clause of the Fourteenth Amendment, Daimler is amenable to suit in California courts for claims involving only foreign plaintiffs and conduct occurring entirely abroad." 134 S. Ct. at 753. The Court concludes by noting that "the transnational context of this dispute bears attention," *id.* at 762, which the Court explains by noting that foreign policy concerns were implicated by the Ninth Circuit's "uninhibited approach to personal jurisdiction." *Id.* at 763. It also bears noting that *Daimler* does not mention consent. Thus, while I have previously recognized the impact of the "at home" concept when Central American banana plantation workers were suing for injuries caused by pesticide use in Central America, *see Chavez v. Dole Food Co.*, 947 F. Supp. 2d 438, 443 (D. Del. 2013) (holding that Chiquita, a New Jersey corporation, was not at home in Delaware), *appeal pending*, No. 13-4144 (3d Cir.), I do not think it appropriate for me to "overrule" Supreme Court precedent that the Supreme Court has not overruled. *See Forest Labs*, 2015 WL 880599, at *7.

Since Mylan Pharmaceuticals Inc. had complied with the Delaware registration statutes, I find that it consented to general jurisdiction.[6] Since Mylan Inc. did not comply with the Delaware registration statutes, it has not consented to general jurisdiction. (No. 14-777-RGA, D.I. 33, p.1 ("there are no substantive factual differences [between these cases and *Acorda*]).

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[6] One of the Supreme Court's concerns in *Daimler* was predictability, which is enhanced by "'[s]imple jurisdictional rules.'" *Daimler*, 134 S. Ct. at 760 (citation omitted). It was entirely predictable that Mylan Pharmaceuticals Inc. could be and would be sued in Delaware. *See Acorda*, 2015 WL 186833, at *17. I think the Supreme Court used "predictability" with the implied gloss that there should be a very limited number of places in which general jurisdiction exists. It may be the case that at some point the Supreme Court will decide that "consent to general jurisdiction" registration statutes such as Delaware's violate due process or the commerce clause, but that has not happened to date.

Further, there is no basis to conclude that there is general jurisdiction over Mylan Inc. based on some other theory. *See Acorda*, 2015 WL 186833, at *7. Thus, I do not need to decide specific jurisdiction as to Mylan Pharmaceuticals Inc. I need, however, to consider specific jurisdiction as to Mylan Inc.

One of the issues that makes Mylan's arguments that there is no specific jurisdiction in Delaware plausible is that the act of infringement that gives rise to an ANDA suit is "artificial." Nothing actually happens that would give rise to any patent litigation absent the ANDA process. Mylan argues that since nothing really happens, there should be very limited venue choices. Mylan must concede that if it actually were being sued for infringement based on sales, it could be sued on a specific jurisdiction theory anywhere it makes sales. In Mylan's case, that would generally be in any of the fifty states. Thus, Mylan's view of the ANDA process is that it stands in stark contrast to regular patent litigation in terms of venue options. I am not sure that it would make any particular sense that "artificial" patent litigation against Mylan could only be brought in West Virginia, while regular patent litigation can be brought anywhere.

Mylan's view of Novartis's position is that Novartis could bring the suit in any state. (D.I. 36, p.14 n.7). Novartis does not take issue with that factual assertion. (D.I. 38, p.6). That foreign nationals, suing foreign corporations for acts occurring abroad, cannot do so, consistent with due process, in all fifty states, *see Daimler*, does not necessarily mean that domestic corporations with national business operations cannot sue their similarly-situated competitors, consistent with due process, in all fifty states for activities that the competitor wants to occur in all fifty states, and which are part and parcel of their nationwide competition.

One difficulty with Mylan's view is that ANDA litigation often involves multiple generic

filers. If Mylan is right, then Novartis has to sue Zydus in New Jersey, Mylan in West Virginia, and Noven in either Delaware or Florida. Three different district judges, and likely three different magistrate judges. Not very efficient![7] Further, about half of my ANDA trials have had multiple defendants, which also results in efficiencies. For example, the first two rivastigmine transdermal patch trials were supposed to be one four-day trial, but when, at the last moment, the two defendants were severed, the two separate trials were two days and three days, or one extra day.

The difficulty with Novartis's view is that a branded drug company (as a practical matter) gets to select the forum, which could be any state, and, from that wide choice, will pick the forum that works best for it, which may not be the most logical place to litigate.

It seems to me that the legislation establishing the ANDA process could have specified venue, by almost any formula, including, for example, all suits must be filed in Washington, D.C. It would be a company's voluntary choice to participate in the ANDA process. If a company were not to want to be sued in the District of Columbia, it would not have to make ANDA filings. Thus, when a company chooses to use the ANDA process, it would be consenting to all of the rules of the process, including that the suit be filed in the District of Columbia.

While there are interesting issues about specific jurisdiction in this case, I am going to take a simpler approach. I note that in neither *AstraZeneca* nor *Forest Labs* was Mylan Inc. named as a defendant. Thus, the only case that considers whether there is specific jurisdiction over Mylan Inc. is *Acorda*. Further, while Mylan Inc. was named as a defendant in *Acorda*, once

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[7] To contribute further to inefficiency, one could add administrative patent judges simultaneously handling IPRs covering closely related issues.

jurisdictional discovery was allowed, the parties agreed to a stipulated dismissal. (No. 14-935-LPS, D.I. 39). It thus appears that whether Mylan Inc. is a named defendant may not be all that important. *See* No. 14-777-RGA, D.I. 34, p.3 (Novartis: "Mylan Inc. does not appear to be a necessary party"). The *Acorda* specific jurisdiction analysis as to Mylan Inc. logically would apply to these two cases too. There are no significant differences in the record. (No. 14-777-RGA, D.I. 33, p.1). Thus, while I am not bound to follow *Acorda*, it is the only Delaware case on point on this issue, and I believe it would be appropriate to follow *Acorda*'s analysis. *See Acorda*, 2015 WL 186833, at *19. I therefore adopt the analysis, and I too will permit jurisdictional discovery.

Thus, I will deny the motions to dismiss as they pertain to Mylan Pharmaceuticals Inc., and I will dismiss them without prejudice as to Mylan Inc. I will allow sixty days of jurisdictional discovery. At the end of it, Mylan Inc. may renew its motions to dismiss if it so chooses, and, if it does so, shall file a new brief incorporating whatever relevant facts have been learned through the jurisdictional discovery.

I think this is an important issue to get resolved in the Court of Appeals. Branded companies are probably going to keep suing generic companies in districts in which the generic company is not "at home." Wasteful duplicative litigation is going to be pursued, as it has been in some of the Mylan cases and the Zydus case. I realize that the Court of Appeals probably does not need multiple cases presenting the same issue, but I also believe that the Court's discretionary decision-making in whether to accept one of these cases for interlocutory appeal might be assisted in knowing that there are a lot of them. Thus, if either side wants a certification for interlocutory appeal, I request the parties submit a joint proposed order.

It is my intention to proceed with these cases. The parties are requested to submit a status report within one week.

March 16, 2015
Date

Richard G. Andrews
United States District Judge